OCT 2 8 2011

Section 15 – 510(k) Summary

#K 111693

1. **Date Summary Prepared**

   June 8, 2011

2. **Submitter's Name and Address**

   Philips Medical Systems, Heartstream
   2301 Fifth Avenue, Suite 200
   Seattle, WA 98121-1825

3. **Contact Person**

   Tamara Yount
   Senior Regulatory Affairs Specialist
   Telephone: 206.664.5000
   Facsimile: 206.664.5001

4. **Device Name and Classification Panel Information**

   Proprietary Name: Philips HeartStart Model 861388 (text and graphics only) and Model 861389 (ECG) AEDs
   Common Name: Automated External Defibrillator
   Classification Name: Automated External Defibrillator

   Device Classification: Class III pre-amendment (primary)
   Class II (secondary)

   Regulations: Automated External Defibrillator, 21 § 870.5310 (primary)
   Low energy DC Defibrillator, 21 § 870.5300 (secondary)

   Product Code: MKJ (primary)
   LDD (secondary)

5. **Predicate Devices**

   The design technology and intended use of the models 861388 and 861389 are substantially equivalent in safety and performance to the previously cleared Philips

HeartStart FRx AED (#K05004), Philips HeartStart FR2/ FR2+ AED (#K003565, #K003819, #K014157 and #K051632) and Philips SMART Pads III (#K072812).

6. Device Description

These battery powered, automated external defibrillators are available in two models, one with ECG (model 861389) and the other in text only (model 861388). Both models include the Philipis SMART biphasic, impedance-compensating exponential waveform and a multi-parameter Patient Analysis System (PAS) algorithum for determining if the rhythm is shockable. The models 861389 and 861388 deliver a nominal 150J to adults and a nominal 50J to infants and children when the optional infant/child key mode is used. As with previous generations of Philips AEDs, the models 861389 and 861388 have several methods of testing themselves and alerting the user if there is a problem. In addition to the periodic self tests performed each time the device is turned on, both models perform power on self tests, runtime self tests, and runtime operation checks. Using voice prompts, text prompts, graphics, audible tones, light emitting diodes (LEDs) and buttons, the responder is guided through the event.

The models 861388 and 861389 are compatible with several accessories. These items including the Smart Pads III, the Infant/Child Key, a non-rechargeable training battery, an optional Bluetooth transceiver module, an optional data card, an optional language card and various carry cases.

7. Intended Use

The models 861389 and 861388 are compact, lightweight, battery powered automated external defibrillators designed for use by responders who have been trained in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized emergency medical response program. The models 861389 and 861388 are used to treat suspected victims of ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). Both models are used with disposable defibrillator pads applied to potential victims of SCA with the following symptoms:

- Unresponsiveness
- Absence of normal breathing

If in doubt, apply the pads.

The models 861389 and 861388 are intended for adults and children over 55 pounds (25 kg) or 8 years old. Both models are also intended for children under 55 pounds (25 kg) or 8 years old when used with the optional Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child's age or weight, do not delay treatment.

8. Comparison of Technology Characteristics

The waveform used in the models 861389 and 861388 are similar to the FRx and FR2+ in terms of specifications, nominal energy and peak current. Like the FRx and FR2+, models 861389 and 861388 use a similar algorithm to determine shock recommendations. Like the FR2+, the models 861389 and 861388 have a SMART CPR algorithm that supports the CPR First function.

9. Data Used in Determination of Substantial Equivalence

The models 861389 and 861388 employ many of the same technologies as those used in the predicate devices. Testing demonstrates that the models 861389 and 861388 perform in a manner substantially equivalent to the predicates and do not raise any new issues of safety or effectiveness.

10. Conclusion

The introduction of the models 861389 and 861388 does not present any new issues of safcty or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 12 2011

Philips Medical Systems
c/o Ms.Tamara Yount
Senior Regulatory Affairs Specialist
2301 5th Avenue, Suite 200
Seattle, WA 98121

Re: K111693
Trade/Device Name: HeartStart FR3 Automated External Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ and LDD
Dated: October 18, 2011
Received: October 19, 2011

Dear Ms. Yount:

This letter corrects our substantially equivalent letter of October 28, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 12 - Indications for Use

510(k) Number (if known)

#K 111693

Device Name

Philips HeartStart Automated External Defibrillator (AED), Models 861388 and 861389

Indications for Use

The Models 861388 and 861389 are intended for use by trained responders to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). The Models 861388 and 861389 are used with disposable defibrillator pads applied to potential victims of SCA with the following symptoms:

- Unresponsiveness
- Absence of normal breathing

If in doubt, apply the pads.

The Models 861388 and 861389 are intended for adults and children over 55 pounds (25 kg) or 8 years old. The Models 861388 and 861389 are also intended for children under 55 pounds (25 kg) or 8 years old when used with the optional Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child's age or weight, do not delay treatment. Apply the pads as illustrated for a child and use the defibrillator.

WARNING: Performance of the SMART CPR AUTO1 and AUTO2 settings for the CPR feature has not been established in patients under 55 lbs (25 kg) or 8 years old.

The Models 861388 and 861389 are intended for use by personnel who have been trained in its operation and qualified by training in basic life support (BLS), advanced life support (ALS) or other physician-authorized emergency medical response.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 12/2/2011

Division of Cardiovascular Devices

510(k) Number K111693
